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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/609,194 | 06/26/2003 | Daniel J. Potter | 11533US.00 | 7602 |
| 36802 | 7590 | 05/14/2008 | [REDACTED] | EXAMINER |
| PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221 | | | [REDACTED] | BHATIA, AARTI |
| | | | [REDACTED] | ART UNIT |
| | | | [REDACTED] | PAPER NUMBER |
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| | | | 05/14/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/609,194 | POTTER, DANIEL J. | |
| | Examiner | Art Unit | |
| | AARTI BHATIA | 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 August 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

This Office Action is based on the 10/609,194 application filed on 06/26/2003.

Claims 1-12, as amended on 8/13/2007, are currently pending and have been considered below.

Response to Amendment

Claim Objections

1. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Currently claim 9 recites language directly from claim 1, on which claim 9 depends (via claim 8).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 7,101,353 to Lui et al.

Lui discloses the following:

1. A tearable hemostasis valve, comprising: a valve body (11); a first and second grip tab (40) attached to said valve body at a first and second point; a score line (56) disposed on said valve body between said first and second points; a first membrane (27) disposed within said valve body; and a snap-fit arrangement coupled to a distal end of said valve body (see 120 in figure 35), wherein the snap and fit arrangement is adapted to couple onto an outer surface of an annular hub of a proximal end of a tubular medical device (see figures 34 and 35), wherein said snap-fit arrangement comprises a cavity (128) disposed in said valve body; and an annular sidewall (120) defining an opening in communication with said cavity, wherein a diameter of said opening (14) is less than a diameter of said cavity (122).

2. The valve of claim 1, wherein said first membrane is bonded to said valve body.

3. The valve of claim 1, wherein said first membrane is integrally formed with said valve body.

4. A tearable hemostasis valve, comprising: a valve body (11); a first grip tab (40) attached to said valve body; a second grip tab (40) attached to said valve body, (it is the Examiner's position that the interior of the grip tabs contact the valve body in the general center area of the valve assembly, the center axis being substantially a common point for the grip tabs to meet); a score line (56) disposed on said valve body and extending inwardly from the common point toward a longitudinal axis of the valve body; a first membrane (27) disposed within said valve body; and a snap-fit arrangement (120) attached to said valve body.

5. The valve of claim 4, wherein: said first membrane comprises a material of a first durometer (silicone); and said valve body comprises a material of a second durometer (SILASTIC®), said second durometer higher than said first durometer.

6. The valve of claim 5, further comprising a score (29) in said first membrane.

7. The valve of claim 5, further comprising a second membrane (28) disposed within said valve body parallel to said first membrane.

8. The valve of claim 7, wherein said first and second membranes are self-sealing (column 8, lines 49-58).

9. The valve of claim 8, wherein said snap-fit arrangement comprises: a cavity disposed in said valve body; and an annular sidewall defining an opening in communication with said cavity, wherein a diameter of said opening is less than a diameter of said cavity (see claim 1).

10. The valve of claim 9, wherein said annular sidewall is flexible (it is the Examiner's position that there is some level of flexibility inherent in the sidewall).

11. The valve of claim 9, wherein said opening is located below said cavity (see figure 35).

12. The valve of claim 9, wherein said opening is located along one side of said cavity (see figure 35).

Response to Arguments

4. Applicant's arguments filed 8/13/2007 have been fully considered but they are not persuasive.
5. The Examiner has withdrawn the rejection to the claim 21, and the objection to the drawings in view of the Applicant's amendment thereby cancelling claim 21 and amending claim 4, respectively.
6. The Applicant argues that Lui fails to teach a snap-fit arrangement comprising a cavity in the valve body. The Examiner disagrees. Although the present invention is drawn to a hemostatic valve that snap-fits **only over** the medical tube, and Lui teaches a hemostatic valve that snap-fits **both over and into** the medical tube, the disclosure of Lui teaches all limitations as worded in the current claims (see above).
7. The Examiner withdraws the rejection of Heck in view of the amendment to claims 1 and 4. Heck teaches a snap-fit arrangement at the distal site of the splittable hemostatic valve. However, the arrangement is rectangular instead of annular, as now required by the amended claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARTI BHATIA whose telephone number is (571)270-5033. The examiner can normally be reached on Monday-Thursday 8:00am -6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aarti Bhatia/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763